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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental abbreviated new animal drug applications (ANADA's) filed by PennField Oil Co. The ANADA's provide for a zero-day withdrawal period for use of oxytetracycline hydrochloride (OTC HCl) soluble powder in the drinking water of turkeys and for an additional package size.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed two supplements to ANADA 200–026. One supplement provides for a zero-day withdrawal period for turkeys using PennField Oil Co.'s Oxytetracycline HCl–343 (oxytetracycline hydrochloride) treated drinking water. The other supplement provides for use of a package containing 512 grams of OTC HCl per 23.9 ounces of soluble powder for making medicated drinking water for cattle, swine, sheep, chickens, and turkeys. The medicated drinking water is used for the control and treatment of bacterial infections caused by oxytetracycline susceptible organisms.

The supplemental ANADA's are approved as of February 5, 1999, and 21 CFR 520.1660d(a)(8) and (d)(1)(ii) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1660d is amended in paragraphs (a)(8), (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), and (d)(1)(ii)(C)(*3*) by adding a sentence to the end of each paragraph to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(8) * * * Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) * * *

(*3*) * * * Zero-day withdrawal for those products sponsored by No. 053389.

(B) * * *

(*3*) * * * Zero-day withdrawal for those products sponsored by No. 053389.

(C) * * *

(*3*) * * * Zero-day withdrawal for those products sponsored by No. 053389.

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Dated: Feb 26, 1999
February 26, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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